

**REMARKS**

Claims 9-11 and 14-17 are pending in the present application and are rejected. Claims 9, 11, 15 and 17 are herein amended.

**Applicants' Response to Comments in the Advisory Action**

The Advisory Action dated April 17, 2009 indicates that the proposed amendments filed after final rejection will not be entered because they raise new issues that would require further consideration and/or search. Specifically, the Advisory Action refers to claim 9 reciting "increasing linear gradient" (line 7) and "the the" (line 11), method claim 15 not having antecedent basis for "the second side" (line 5), and being an incomplete method for preparing the composite material of claim 9.

With respect to "the the" referred to as being on line 11 of claim 9, this appears to be an error, since claim 9 has no such language. However, Applicants noticed that claim 9 recited the word "side" twice, which Applicants correct in the enclosed amended claims. As to claim 15 not having antecedent basis for "the second side," Applicants note that claim 15 depended on claim 9, which recites "a second side." It appears that the dependent nature of claim 15 was ignored, and that it is preferable for claim 15 to recite "a first side" and "a second side." In order to expedite examination, Applicants herein further amend claim 15 such that it is an independent claim, and recites "a first side" and "a second side." Additionally, Applicants herein incorporate the remarks of the Amendment filed March 17, 2009, which are reproduced below.

**Applicants' Response to Claim Objections**

The Office Action indicates that Claim 17 is objected to because the claim recites "the scaffold according to claim 9," while claim 9 is drawn to a composite material, not a scaffold. The Office Action states that the claim should be dependent on claim 11.

In response, Applicants herein amend claim 17 to be dependent on claim 9, but to recite a scaffold that includes the composite material of claim 9. Favorable reconsideration is respectfully requested.

**Applicants' Response to Claim Rejections under 35 U.S.C. §112**

**Claims 15 and 17 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

With respect to claim 15, it is the position of the Office Action that claim 15 is indefinite because it does not claim "a complete method" containing all steps needed to produce a composite as required by claim 9. The Office Action states that in addition to alternatively soaking the polymeric material, the method should comprise the step of "providing a polymeric material selected from the group of claim 9."

In response, Applicants first respectfully note that it is not required that the claims recite "a complete method." Rather, the minimal requirement is that the claims recite the essential subject matter of the method. However, in order to advance prosecution and satisfy the request

in the Office Action, Applicants herein amend claim 15 to recite a step of providing a polymeric material. Please see amended claim 15.

As to claim 17, it is the position of the Office Action that the term “composition gradient” does not have proper antecedent basis, since the term “composition gradient” was removed from claim 9. Therefore, Applicants herein amend claim 17 to recite “the gradient.” Please see amended claim 17. Favorable reconsideration is respectfully requested.

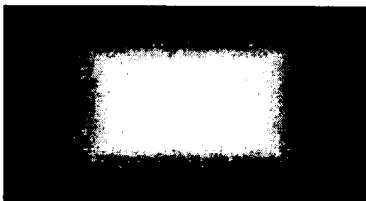
**Applicants’ Response to Claim Rejections under 35 U.S.C. §103**

**Claims 9-11 and 14-17 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Mattern et al. (6,969,523) or Yannas et al. (4,947,840) in view of Akashi et al. (6,387,414) and Sherwood et al. (6,454,811), and if necessary in further view of Taguchi et al. (Biomaterials).**

It is the position of the Office Action that Mattern or Yannas discloses the embodiment as claimed with the exception of forming the composite by alternatively soaking the material in a calcium ion-containing solution and a phosphate ion-containing solution. The Office Action relies on Akashi to provide this teaching. The Office Action additionally relies on Sherwood to teach a gradient generally. The Office Action also optionally relies on Taguchi to teach alternative soaking of a film in a calcium ion-containing solution and a phosphate ion-containing solution.

In response to Applicants’ previously filed remarks that the cited art does not disclose or suggest the embodiments as claimed because it only discloses alternatively soaking the whole

material (rather than one side thereof) in the calcium ion-containing solution and phosphate ion-containing solution, the pending Office Action states that a gradient can be formed with such a soaking of the whole material. The Office Action interprets the claims to include soaking one side of the material and another side of the material. Thus, the Office Action interprets the claims to include soaking the entire material in the solutions. The Office Action further states that the soaking of the entire matrix as in Akashi or Taguchi would result in a gradient that “can extend from the entire surface of the matrix towards the center of the matrix.” Thus, it appears that the Office Action interprets the claims prior to amendment such that they could include a matrix having a cross-section as illustrated in the simplified diagram below, and alleges that the cited art discloses such a matrix.



However, the subject matter of the application is directed at a composite that has a gradient of calcium phosphate from one side to the other with an increasing linear gradient. This gradient is formed by alternatively soaking only one side of the composite in the calcium ion-containing solution and the phosphate ion-containing solution. The other side of the composite is not soaked in either solution. Thus, the composite of the present invention has a cross-section represented by the illustration of the simplified diagram below.



Accordingly, Applicants herein amend the claims in order to clarify this difference from the cited art. In order to do so, Applicants herein amend claim 9 to recite that the gradient is “from a first side of said biodegradable polymeric material to a second side of said biodegradable polymeric material with an increasing linear gradient.” This subject matter is supported at least by page 6, lines 4-6.

As noted above, the cited art only discloses alternatively soaking the whole material in the solutions. However, the cited art does not disclose soaking only one side of the material. The soaking disclosed in the cited art necessarily imparts the structural feature of a gradient which increases toward the exterior of the material—in other words, adsorption. However, the cited art does not disclose or suggest the embodiment of amended claim 9, where the gradient increases from one side to the other side. Therefore, Applicants respectfully submit that the cited art does not disclose or suggest the embodiment of claim 9, and all claims dependent thereon.

Additionally, in order to clarify the claimed subject matter, Applicants herein amend the claims to recite that the gradient increases from the first side of the material to the second side of the material. Thus, the second side of the material contains more of the calcium phosphate than the first side. For this reason, Applicants herein recite soaking the second side of the material in

the solutions. Therefore, the amended claims require that the side which is soaked is the side which has the greater amount of calcium phosphate.

As to claims 10, 11, and 14-17, Applicants respectfully submit that these claims are patentable at least due to their dependency on claim 9, which Applicants submit is patentable for at least the above reasons. Favorable reconsideration is respectfully requested.

**Claims 9, 15, 16, and 17 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Akashi et al.**

It is the position of the Office Action that Akashi discloses the embodiments as claimed, with the exception of teaching using collagen as a matrix. The Office Action alleges that it would have been obvious to modify Akashi to use collagen as a matrix.

In response, Applicants respectfully submit that these claims are patentable over Akashi for similar reasons as to why they are patentable over the combination of Mattern/Yannas, Akashi, Sherwood, and optionally, Taguchi. That is, the cited art does not disclose or suggest a material having the gradient as claimed. Favorable reconsideration is respectfully requested.

**Claims 10, 11 and 14 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Akashi et al. in view of Mattern et al. or Yannas et al.**

Application No.: 10/516,818  
Art Unit: 1657

Amendment under 37 CFR 1.114  
Attorney Docket No.: 043070

It is the position of the Office Action that Akashi discloses the embodiments as claimed, with the exception of teaching that the polymeric material is a crosslinked product of glycosaminoglycan and collagen. The Office Action relies on Mattern or Yannas to provide this teaching.

In response, Applicants respectfully submit that these claims are patentable over Akashi for similar reasons as to why they are patentable over the combination of Mattern/Yannas, Akashi, Sherwood, and optionally, Taguchi. That is, the cited art does not disclose or suggest a material having the gradient as claimed. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

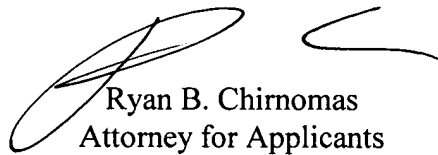
Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

Application No.: 10/516,818  
Art Unit: 1657

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If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,  
**WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP**



Ryan B. Chirnomas  
Attorney for Applicants  
Registration No. 56,527  
Telephone: (202) 822-1100  
Facsimile: (202) 822-1111

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